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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,288	11/13/2001	Frans Gerrit Davelaar	AHP-98249	5326

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,288	DAVELAAR, FRANS GERRIT	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant amended claims 1, 10, 12, 13, 15, 16, 18, 21 and 22. Claims 1-22 are under consideration.

It is noted on page 2 of the response that applicant states that original claim 18 was dependent upon claim 17 and not claim 1, as per the Office action on page 3. The examiner appreciates the amendment to the claim as well as the clarification that original claim 18 did have antecedent basis. The first sentence on page 3 of the previous Office action stated that claim 18 recited a limitation "in 1". "1" was intended to refer to the line number of original claim 18. The examiner apologizes for this inadvertent typo.

The amendments to the claims presented by applicant obviates previous objections to the claims as well as the rejections under 35USC § 112, second paragraph and the rejection of claims 10-14 under 35USC § 112, first paragraph. Applicant has also obviated the rejection under 35USC § 112, first paragraph regarding claims 19-21 by amendments to the claims as well as pointing to a specific definition on page 4, lines 8-17 of the disclosure stating that the percent hatchability claimed is relative to the hatchability in a control group, as well as the data presented in working examples 1 and 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-15, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Poston et al. (WO 99/53950).

(It is noticed in the previous Office action on page 5, that the body of the rejection inadvertently included claim 2, even though the specific limitations of the claim were not discussed or listed in the first paragraph of the rejection. The inclusion of claim 2 in the second paragraph on page 5 was obviously a typo.)

Claims 10-14 are currently included in the instant rejection due to present amendments to the claims. The claims are drawn to a process for protecting turkeys or chickens against infection from exposure to virulent strains of turkey rhinotracheitis virus by *in ovo* administration of a live, avirulent strain of the virus, where the administration results in a decrease in the percent of eggs that hatch of substantially no decrease or a decrease of less than about 2%. The claims further state that the amount of virus administered is between $10^{3.2}$ to about $10^{4.2}$ $TCID_{50}$ per egg.

In addition, upon further consideration of claims 19-21, it is determined that Poston et al. also anticipate the limitations of these claims. The claims state that the method of inoculating turkeys results in substantially no decrease in the number of eggs that hatch, or that the decrease is less than 5% or 1%.

Poston et al. clearly demonstrate several inoculations with various concentrations of virus and interferon *in ovo* to protect avians against infection due to exposure and improve hatchability relative to a control group of eggs. The concentration of virus administered by Poston et al. is equivalent to a point within the instant range claimed. For example, in working example 15 on page 34, Poston et al. administer $10^{3.5}$ EID_{50} of virus along with interferon. This administration

results in an approximate 45% improvement in the hatchability of chicks that received the same amount of virus alone, see Figure 14. Therefore, the teachings of Poston et al. also anticipate claims 10-14 and 19-21.

Claims 1, 3-9, 15, 17 and 18 remain rejected for reasons of record.

In response to the rejection, applicant argues that Poston et al. do not anticipate the instant claims because Poston et al. require the administration *in ovo* of interferon along with the virus. Applicant asserts that Poston et al. do not describe a method of protecting an avian host against a viral infection in the absence of interferon or administering a live, attenuated TRT virus.

Applicant's arguments have been fully considered, but are found unpersuasive. The instant claims are drawn to a method of protecting an avian host *in ovo* by administering a vaccine to an embryo-containing, fertilized egg, said vaccine comprising an immunologically-effective amount of a live, attenuated strain of TRT virus (emphasis added). Since the instant vaccine "comprises" at least one component, i.e. the live, attenuated strain of TRT, the instant vaccine in the method does not exclude other components from being present in the composition, such as the interferon of Poston et al.

Further, Poston et al. do teach a method of protecting an avian subject against TRT by administering a composition comprising a live vaccine virus, which includes TRT and interferon to an avian subject, such as turkeys or chickens in the last quarter of *in ovo* incubation, see the previous citations as well as claims 1, 6, 7, 11 and 14 for example. On page 11, lines 10-13, Poston et al. specifically teach that vaccine viruses used in the method include commercial, live virus vaccines. These live viral vaccines that are available commercially include viruses that are

attenuated. Poston et al. specifically list turkey rhinotracheitis virus as a suitable virus that is used in the method, see page 12, lines 4-5. Therefore, Poston et al. anticipate every element instantly claimed.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Poston et al., *supra* for reasons of record.

Applicant argues that claim 16 is not anticipated or rendered obvious by Poston et al. since an essential element in the reference, interferon, is missing from the instant claims. Applicant asserts that every embodiment of Poston et al. includes the use of interferon.

Applicant's arguments have been fully considered, but are found unpersuasive. It is agreed that Poston et al. require the presence of interferon in combination with viruses for use in the methods disclosed. However, no element, such as interferon, is excluded from the vaccine used in the instant method. Therefore, since Poston et al. teach or explicitly suggest each of the limitations recited in the instant claims, it is maintained that claim 16 is anticipated or rendered obvious by the teachings of Poston et al.

Claims 2 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Poston et al. as applied to claims 1, 3-9, 15, 17 and 18 above, and further in view of Ricks et al. (Advances in Veterinary Medicine. 1999; 41: 495-515, provided in the IDS) for reasons of record.

Applicant argues that Ricks et al. only provide a general background of art-recognized techniques for *in ovo* administration and do not recommend broad application of *in ovo* administration of other pathogenic viruses.

Applicant's arguments have been fully considered, but are found unpersuasive since Ricks et al. is not required to teach elements, such as broad application of *in ovo* administration of pathogenic viruses, that are taught by Poston et al. Additionally, instant claims 2 and 22 do not require the administration of pathogenic viruses, but the administration of a vaccine comprising a live, attenuated strain of turkey rhinotracheitis virus (emphasis added), not a broad spectrum of pathogenic viruses. As discussed above, the vaccine administered by Poston et al. include live, commercially available viruses that are attenuated.

Applicant points to the middle paragraph on page 503 of Ricks et al. and states that Ricks et al. indicate that many posthatch vaccines are unsafe for in ovo administration and that only vaccines approved by APHIS be used in the United States.

A careful review of the reference has been fully considered, but is found unpersuasive. In the citation cited by applicant, Ricks et al. do teach that many of the posthatch vaccines are unsafe for *in ovo* administration. However, this concern is rendered moot by the teachings of Poston et al.

Applicant argues that the combined references do not render the invention obvious because neither reference implies that the *in ovo* method can be used in the absence of interferon.

Applicant asserts that the ordinary artisan would expect that administering TRTV would be harmful to the embryo and would have no motivation to administer TRTV in any suitable amount.

Applicant's arguments have been fully considered, but are found unpersuasive since the instant claims do not exclude any element from the vaccine composition, such as interferon. The claims require administering TRTV *in ovo* to fertilized, embryonated eggs. These required elements are clearly anticipated by Poston et al.

Applicant argues that the instant invention successfully demonstrates *in ovo* administration of a live, pathogenic virus in the absence of high mortality.

The results disclosed by applicant and the teachings of Poston et al. have been fully reviewed and it is determined that there is no difference between them, i.e. no surprising result. It is agreed that Poston et al. require near simultaneous administration of interferon with the vaccine and the instant claims do not include this limitation. However, neither the instant claims nor the specification exclude any particular ingredient from the vaccine composition used in the method. Therefore, the addition of interferon required by Poston et al. is also not excluded from the scope of the instant claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Patent Examiner, 1648